

Medi-Cal Rx Monthly Bulletin

April 1, 2023

The monthly bulletin consists of alerts and notices posted to the <u>Bulletins & News</u> page on the Medi-Cal Rx Web Portal. Sign up for the <u>Medi-Cal Rx Subscription Service</u> to be notified when new information is posted.

- 1. Changes to the Contract Drugs List
- 2. Changes to the Contract Drugs List Authorized Drug Manufacturer Labeler Codes
- 3. Updates to the Medi-Cal Rx Provider Manual
- 4. <u>30-Day Countdown Phase III, Lift 1: Retirement of the Transition Policy for Beneficiaries</u> <u>22 Years of Age and Older</u>
- 5. <u>Submitting Prior Authorization Requests in Advance of Retirement of the Transition Policy</u>
- 6. <u>Policy Update of Remdesivir (Veklury) for the Outpatient Treatment of COVID-19 as a</u> <u>Pharmacy Benefit</u>
- 7. <u>Enteral Nutrition Update: Changes to the Published Enteral Nutrition Policy in the</u> <u>Medi-Cal Rx Provider Manual, Effective April 1, 2023</u>
- 8. Maximum Allowable Ingredient Cost 30-Day Pharmacy Provider Notice
- 9. New Resources for Providers: COVID-19 Testing and Treatment Support
- 10. Pharmacy Provider Dispensing Fee Self-Attestation

1. Changes to the Contract Drugs List

The below changes have been made to the <u>Contract Drugs List</u> posted to the Medi-Cal Rx Web Portal, effective April 1, 2023.

Drug Name	Description	Effective Date
Adagrasib	Added to CDL with restriction.	April 1, 2023
Aztreonam Lysine	Removed Code I restriction.	April 1, 2023
Elacestrant	Added to CDL with restriction.	April 1, 2023
Fesoterodine Fumarate	Removed Code I restriction.	April 1, 2023
Mercaptopurine	Additional formulation (oral suspension) added to CDL.	April 1, 2023
Mirvetuximab soravtansine-gynx	Added to CDL with restriction.	April 1, 2023
Nevirapine	Removed Code I restriction.	April 1, 2023
Pirtobrutinib	Added to CDL with restriction.	April 1, 2023
Somatropin (Genotropin)	Added to CDL with restriction.	April 1, 2023
Somatropin (Genotropin MiniQuick)	Added to CDL with restriction.	April 1, 2023
Somatropin (Norditropin FlexPro)	Added to CDL with restriction.	April 1, 2023
Tagraxofusp-erzs	Added to CDL with restriction.	April 1, 2023
Tobramycin	Removed Code I restriction.	April 1, 2023
Ulipristal Acetate	Updated Code I restriction.	April 1, 2023

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2. Changes to the Contract Drugs List - Authorized Drug Manufacturer Labeler Codes

The below changes have been made to the <u>Contract Drugs List – Authorized Drug Manufacturer</u> <u>Labeler Codes</u> with their respective effective dates and posted to the Medi-Cal Rx Web Portal.

Labeler Code Additions:

NDC Labeler Code	Contracting Company's Name	Effective Date
72989	ACERTIS PHARMACEUTICALS	April 1, 2023
71993	ATLAND PHARMACEUTICALS, LLC	April 1, 2023
73289	AUCTA PHARMACEUTICALS, INC.	April 1, 2023
73554	BLUEBIRD BIO, INC.	April 1, 2023
71321	BRANDYWINE PHARMACEUTICALS	April 1, 2023
73358	CURAE PHARMA360 INC.	April 1, 2023
61825	GALT PHARMACEUTICALS LLC	April 1, 2023
72903	IMMUNOGEN, INC.	April 1, 2023
60842	KALEO, INC.	April 1, 2023
71288	MEITHEAL PHARMACEUTICALS INC.	April 1, 2023
80739	MIRATI THERAPEUTICS, INC.	April 1, 2023
73650	PROVENTION BIO, INC.	April 1, 2023
71767	SCPHARMACEUTICALS INC.	April 1, 2023
83035	SINGULAR DREAMER, LTD	April 1, 2023
82584	THEA PHARMA	April 1, 2023
81964	US ANTIBIOTICS	April 1, 2023
82347	YARAL PHARMA INC.	April 1, 2023

Labeler Code Terminations:

NDC Labeler Code	Contracting Company's Name	Effective Date
59917	ADARE PHARMACEUTICALS, INC.	April 1, 2023
52609	APO-PHARMA USA, INC.	April 1, 2023
00087	BRISTOL-MYERS SQUIBB COMPANY	April 1, 2023
70363	CUTANEA LIFE SCIENCES LLC	April 1, 2023
72763	ESTRENO PHARMACEUTICALS LLC	April 1, 2023
10885	GALEN US INCORPORATED	April 1, 2023
72721	HEARTWOOD PHARMA	April 1, 2023
49938	JACOBUS PHARMACEUTICALS CO INC.	April 1, 2023
66435	KADMON PHARMACEUTICALS, LLC	April 1, 2023
58407	MAGNA PHARMACEUTICALS, INC.	April 1, 2023
00015	MEAD JOHNSON AND COMPANY	April 1, 2023
72171	NOVIMMUNE S.A.	April 1, 2023
58463	PRAGMA PHARMACEUTICALS, LLC	April 1, 2023
40085	RENAISSANCE PHARMA, INC.	April 1, 2023
70655	RENAISSANCE SSA, LLC	April 1, 2023
00145	STIEFEL LABORATORIES, INC.	April 1, 2023

3. Updates to the Medi-Cal Rx Provider Manual

The updates/additions below have been made to the Medi-Cal Rx Provider Manual version 6.0.

Updates

Section	Update Description	Effective Date
Section 4.6.13 – Medical Supply Reimbursement	Updated language.	April 1, 2023
Section 16.2 – Patient Counseling Requirements	Updated language addresses consultation requirements.	April 1, 2023

30-Day Countdown – Phase III, Lift 1: Retirement of the Transition Policy for Beneficiaries 22 Years of Age and Older

What Pharmacy Providers and Prescribers Need to Know

As announced in the alert titled <u>90-Day Countdown – Phase III: Retirement of the Transition</u> <u>Policy for Beneficiaries 22 Years of Age and Older</u>, Medi-Cal Rx will initiate the first of a series of transition policy lifts for beneficiaries 22 years of age and older starting March 24, 2023. A transition lift is the retirement or phasing out of the Transition Policy for identified Standard Therapeutic Classes (STCs) that "lifts" the override of **NCPDP Reject Code 75 – Prior Authorization Required**. The following STCs will be impacted by the first transition lift of Phase III, beginning March 24, 2023:

Phase III, Lift 1 (P3/L1) Drug Classes *		
Diuretics	Anti-Lipemic Agents	Hypoglycemics
(STC 79, 53)	(STC 65, 66)	(STC 58)
Antihypertensives	Coronary Vasodilators	Cardiovascular Agents
(STC 71)	(STC 72)	(STC 76, 74)
Anticoagulants and	Niacin, Vitamin B and	Opioids
Antiplatelets	Vitamin C	(STC 40)
(STC 77)	(STC 81)	Benzodiazepines
		(HIC3: H20, H21, H22, H4A,
		H8G, H8K) **

* STC refers to the Standard Therapeutic Classification number. Hierarchical Ingredient Code 3 (HIC3) refers to the Specific Therapeutic Classification per First DataBank (FDB).

** Listed HIC3s fall within STCs 07, 47, and 48; other drugs within these STCs are not impacted by this transition lift. Refer to the P3L1 NDCs tab in the <u>Medi-Cal Rx Approved NDC List</u> for additional detail.

 Beneficiaries 21 years of age and younger are exempt from the Phase III Transition Policy retirement. Enteral nutrition products for beneficiaries of all ages are also exempt from Phase III Transition Policy retirement.
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What Pharmacy Providers and Prescribers Need to Do

If a beneficiary is currently receiving a medication in the STCs that are impacted by P3/L1 as outlined in the table above, pharmacy providers and prescribers should prepare for the retirement of the Transition Policy in the following ways:

- 1. Consider covered therapies that may not require a prior authorization (PA), if clinically appropriate. Review the following:
 - Medi-Cal Rx Contract Drugs Lists & Covered Products Lists
 - Medi-Cal Rx Approved NDC List
 - Prescribers: Refer to your ePrescribing application.
- If a change in therapy is not appropriate, submit PA requests beginning February 24, 2023.
 PA requests can be submitted via the Medi-Cal Rx Submission Methods:
 - <u>CoverMyMeds®</u>
 - Medi-Cal Rx Secured Provider Portal
 - NCPDP P4 Transaction
 - Fax
 - U.S. Mail

Resources

- For more information about Medi-Cal Rx Reinstatement, visit the <u>Medi-Cal Rx Education &</u> <u>Outreach</u> page on the <u>Medi-Cal Rx Web Portal</u> and select **Medi-Cal Rx Reinstatement**.
- Review the <u>Medi-Cal Rx Reinstatement of Prior Authorizations and Retirement of the</u> <u>Transition Policy: Phases II, III, and IV</u> slide deck.
- Review Medi-Cal Rx Phased Reinstatement Frequently Asked Questions (FAQs).
- Review the <u>Medi-Cal Rx Reinstatement Phase II and Preparation for Retirement of the</u> <u>Transition Policy</u> webinar recording.
- Refer to the <u>Medi-Cal Rx Bulletins & News</u> and <u>Medi-Cal Rx Forms & Information</u> pages of the <u>Medi-Cal Rx Web Portal</u> for guidance to successfully submit PAs.

5. Submitting Prior Authorization Requests in Advance of Retirement of the Transition Policy

What Pharmacy Providers and Prescribers Need to Know

As of February 24, 2023, Medi-Cal Rx accepts renewal prior authorizations (PAs) in advance of the retirement of the Transition Policy for medications and/or products for beneficiaries

22 years of age and older (excluding enteral nutrition products). Pharmacy providers and prescribers do not have to wait for each respective Transition Policy lift within Reinstatement Phase III to submit PAs to Medi-Cal Rx for drug/product refills. As a reminder, PA requests are reviewed for medical necessity, and pharmacy providers and prescribers should include all relevant clinical information on the request. The alert titled <u>Reminder: Establishing Medical</u> <u>Necessity</u> provides guiding information.

- PA requests for beneficiaries 21 years of age and younger are not accepted at this time.
 - PA requests for enteral nutrition products for beneficiaries of any age are not accepted at this time.

What Pharmacy Providers Can Do

If a claim pays with the following supplemental message, this claim is eligible for PA submission as of February 24, 2023: "The Medi-Cal Rx transition policy will be retired in a series of transition lifts, starting on 3/24/2023. A Prior Authorization may be required for this benefit/drug. Consider submitting a PA today. For more information, please visit the Medi-Cal Rx website."

Additionally, pharmacy providers can notify the beneficiary and/or prescriber that a PA will be required for this drug/product at a later date.

What Prescribers Can Do

If a beneficiary has been receiving a drug/product that is not on the <u>Medi-Cal Rx Contract</u> <u>Drugs List or Covered Product Lists</u>, prescribers can submit a PA to Medi-Cal Rx for this drug/product in advance of the PA end date and/or retirement of the Transition Policy. Prescribers may also consider switching the beneficiaries' prescription to a medication or product that does not require a PA, if clinically appropriate.



Unless otherwise indicated on the PA request, the PA start date is the date the PA was signed and submitted to Medi-Cal Rx.

Resources

- Refer to the <u>Medical Supplies: How to Prepare for Retirement of the Transition Policy</u> and <u>How to Prepare for Retirement of the Transition Policy</u> alerts for more information related to submitting a PA in advance of the retirement of the Transition Policy.
- For more information regarding the retirement of the Transition Policy, refer to the <u>90-Day</u> <u>Countdown – Phase III: Retirement of the Transition Policy for Beneficiaries 22 Years of Age</u> <u>and Older</u> alert.
- Refer to the Medi-Cal Rx Contract Drugs & Covered Products Lists.
- For more information about Medi-Cal Rx Reinstatement, visit the <u>Medi-Cal Rx Education &</u> <u>Outreach</u> page on the <u>Medi-Cal Rx Web Portal</u> and select **Medi-Cal Rx Reinstatement**.

Policy Update of Remdesivir (Veklury) for the Outpatient Treatment of COVID-19 as a Pharmacy Benefit

Effective immediately, the Department of Health Care Services (DHCS) will no longer require a prior authorization (PA) for the reimbursement of Veklury as a pharmacy benefit.

Veklury is an antiviral drug that has been approved by the U.S. Food and Drug Administration (FDA) for the treatment of adults and pediatric patients (28 days of age and older and weighing at least 3 kg) with positive results of SARS-CoV-2 viral testing. Veklury is for people who are hospitalized or not hospitalized with mild to moderate COVID-19 symptoms and are at high risk for progression to severe COVID-19, including hospitalization or death.

Initially, Veklury was FDA-approved for the treatment of hospitalized adults. On April 25, 2022, the FDA approved Veklury additionally for the treatment of pediatric patients.

Treatment duration for non-hospitalized patients is three days and is initiated as soon as possible after diagnosis of COVID-19, within seven days of symptom onset. See <u>FDA-Approved</u> <u>Drugs: Veklury</u> for a full list of drug specifications.

Veklury should be administered in a hospital or a health care setting with immediate access to medications to treat a severe infusion or hypersensitivity reaction, such as anaphylaxis, and the ability to activate the emergency medical system (EMS), if necessary.

Important Billing Instructions

- DHCS will reimburse Veklury for the treatment of COVID-19 when administered in accordance with FDA approval.
- A PA is no longer required. Code I restriction is required, attesting that the provider will meet the following requirements in accordance with FDA approval:
 - Patient meets FDA requirements for age and weight.
 - Patient has a positive result of direct SARS-CoV-2 viral testing.
 - Veklury will be administered in settings where severe hypersensitivity reactions, such as anaphylaxis, can be managed and emergency services activated such as skilled nursing facilities (SNFs), home health care settings, and outpatient facilities such as infusion centers.
 - The treatment course is being initiated within seven days of symptom onset.
 - Must comply with the following testing before initiating and during treatment with Veklury:
 - Renal function tests:
 - Determine estimated glomerular filtration rate (eGFR) before starting
 - Veklury and monitor while receiving Veklury as clinically appropriate.
 - Monitor serum creatinine and creatinine clearance (CrCl).
 - Should not be administered if eGFR is less than 30 mL per minute.
 - Monitor for signs and symptoms of infusion reactions.
 - Hepatic function tests:
 - Monitor alanine aminotransferase (ALT), aspartate aminotransferase (AST), bilirubin, and alkaline phosphatase.

- Avoid use if ALT ≥ 10 times the upper limit of normal (ULN).
- Discontinue use if ALT elevation and signs or symptoms of liver inflammation.
- Hematology:
 - Determine prothrombin time and monitor serum chemistries before starting Veklury and monitor while receiving Veklury.
- Veklury is restricted to a maximum of three days supply per dispensing for each diagnosis. Documentation is required justifying medical necessity for a longer treatment duration.
- All other policy details remain as previously implemented and published.

Resources

- Veklury Package Insert
- <u>Outpatient Product Information Guide.pdf (vekluryhcp.com)</u>
- <u>NIH COVID-19 Treatment Guidelines</u>
- Veklury ordering and access information
 - Hospital ordering process: Hospitals can place orders with any of the following distributors by calling directly:
 - AmerisourceBergen Specialty Distribution: 1-800-746-6273
 - Cardinal Specialty: 1-855-855-0708
 - McKesson Plasma: 1-877-625-2566
 - Nonhospital ordering process: Nonhospitals can contact AmerisourceBergen Specialty Distribution by calling 1-800-746-6273 or emailing

<u>C19Therapies@AmerisourceBergen.com</u> for more information.

For population of claim form fields other than those identified in this guidance, review the <u>Medi-Cal Rx Provider Manual</u>.

Any concerns regarding delay in reimbursement should not cause providers to decline dispensing Veklury to patients.

For more information on services covered by Medi-Cal Rx, providers should refer to the <u>Medi-Cal Rx Web Portal</u>.

Enteral Nutrition Update: Changes to the Published Enteral Nutrition Policy in the Medi-Cal Rx Provider Manual, Effective April 1, 2023

The *Enteral Nutrition* section in the <u>Medi-Cal Rx Provider Manual</u> has been updated on the <u>Medi-Cal Rx Web Portal</u>. These changes are effective on and after April 1, 2023.

If a Medi-Cal Rx prior authorization (PA) request was denied for enteral nutrition products and the beneficiary believes the denial was in error, the beneficiary may ask for a state hearing by contacting the California Department of Social Services, State Hearings Division, at the following address:

P.O. Box 944243, MS 21-37 Sacramento, CA 94244-2430 Toll Free: 1-800-743-8525 or 1-855-795-0634 Fax: 1-833-281-0905

Medi-Cal Rx beneficiaries who are members of a Medi-Cal Managed Care Plan (MCP) can contact their individual plan directly for possible coverage, billed as a medical benefit on a *CMS-1500* medical claim form. Each Medi-Cal MCP determines enteral nutrition coverage outside of Medi-Cal Rx since enteral nutrition is a partial carve out Medi-Cal Rx benefit.

8. Maximum Allowable Ingredient Cost 30-Day Pharmacy Provider Notice

What Pharmacy Providers Need to Know

The Department of Health Care Services (DHCS) has contracted with Magellan Medicaid Administration, LLC (MMA), who contracts with Mercer Government Human Services Consulting (Mercer), to establish and maintain a Maximum Allowable Ingredient Cost (MAIC) program for generic pharmaceutical drugs.

Rates will be effective April 1, 2023, and will be posted to the Mercer Medi-Cal Rx website no later than March 1, 2023.

What Pharmacy Providers Need to Do

- Refer to the Mercer Medi-Cal Rx website for MAIC rate lists, MAIC program information, Frequently Asked Questions (FAQs), and contact information.
- To request a review of a MAIC rate for a specific drug, submit a request using the <u>Medi-Cal Rx Maximum Allowable Ingredient Cost (MAIC) Price Research Request Form</u> found on the <u>Mercer Medi-Cal Rx website</u> and the <u>Medi-Cal Rx Web Portal</u>.

Note: All required fields on the form must be completed. Providers will be contacted for supporting documentation or other information as necessary.

9. New Resources for Providers: COVID-19 Testing and Treatment Support

Medi-Cal Rx is pleased to partner with the California Department of Public Health (CDPH) to announce the publication of new resources to support providers in assessing the need for and the delivery of COVID-19 treatment to Medi-Cal beneficiaries.

- <u>COVID-19 Therapeutics Myths and Facts</u> A two-page flyer providing helpful responses to common COVID-19 myths.
- <u>COVID-19 Test to Treat Frequently Asked Questions (updated February 1, 2023)</u> Frequently Asked Questions (FAQs) and answers concerning testing, treatment, and follow-up care.
- <u>COVID-19 Therapeutics Warmline</u> Announcement of the free and confidential consultation line available to all California health care providers, managed by the University of California, San Francisco (UCSF) National Clinician Consultation Center.

Additional Medi-Cal Rx Resources

- Updates to Over-the-Counter (OTC) COVID-19 Antigen Test Kits, Effective March 1, 2023
- <u>Bebtelovimab No Longer Authorized to Treat COVID-19</u>
- <u>Evusheld® No Longer Authorized to Prevent COVID-19</u>
- <u>Medi-Cal Rx Provider Manual</u>, Section 17.0: COVID-19 Vaccines, OTC Antigen Test Kits, and Therapeutics: Coverage and Reimbursements

10. Pharmacy Provider Dispensing Fee Self-Attestation

What Pharmacy Providers Need to Know

The attestation period to determine the dispensing fees assigned for dates of service (DOS) July 1, 2023 – June 30, 2024 is **March 1, 2023 – March 31, 2023**. Attestations **will not** automatically carry over from the previous year. Pharmacy providers must attest during the attestation period (March 1, 2023 – March 31, 2023) if they believe they are eligible for the higher of the two dispensing fees.

Pursuant to *Welfare and Institutions Code* (W&I Code), Section 14105.45, the professional dispensing fee is based on a pharmacy's total (Medicaid and non-Medicaid) annual prescription volume from the previous year as follows:

- Less than 90,000 claims equals \$13.20
- 90,000 or more claims equals \$10.05

Note: Department of Health Care Services (DHCS) policy is that a claim is equivalent to a dispensed prescription.

What Pharmacy Providers Need to Do

Beginning March 1, 2023, pharmacy providers can complete the attestation survey at <u>https://mercer.qualtrics.com/jfe/form/SV_1Ff9hacRTjy7ixE</u>. You can also access the survey using the individual link sent to you via email. If you received a fax notification, you may also scan the QR Code using a smartphone. The survey password will either be mailed or emailed prior to March 1, 2023. For questions, email <u>CODSurvey@mercer.com</u>.

Only the Medi-Cal pharmacy provider, or a person authorized by the Medi-Cal pharmacy provider to bind the provider by signature to the conditions contained in the attestation statement, may complete the attestation. This may include the pharmacist in charge, the owner, or a direct delegate with authority to contractually obligate the organization.

Resources

Refer to the following resources for dispensing fee self-attestation:

- Pharmacy Provider Dispensing Fee Self-Attestation FAQs
- <u>Pharmacy Provider Dispensing Fee Self-Attestation Webinar (Recording)</u>

Contact Information

You can call the Medi-Cal Rx Customer Service Center (CSC) at 1-800-977-2273, which is available 24 hours a day, 7 days a week, 365 days per year.

For other questions, email Medi-Cal Rx Education & Outreach at <u>MediCalRxEducationOutreach@magellanhealth.com</u>.